UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/466,035	12/17/1999	MATTI SALLBERG	930049.458C1	9697

27476 7590 03/09/2004

Chiron Corporation
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER	
PARAS JR, PETER	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/466,035	SALLBERG ET AL.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,12,13,24 and 26-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 12, 13, 24, and 26-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment received on 12/11/03 has been entered. Claims 1, 5, and 12-13 have been amended. New claims 26-30 have been added. Claims 6-11, 14-23, and 25 have been cancelled. Claims 1-5, 12-13, 24 and 26-30 are pending and are under current consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 24, and 26-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Craig (US 6,689,757).

The claims are directed to a method for generating an immune response against one or more intracellular pathogens within warm-blooded animals comprising

administering to a warm-blooded animal a gene delivery vehicle vector [retroviral vectors, alphavirus vectors, parvovirus vectors, plasmid vectors, or eukaryotic layered initiation system vectors] comprising a polynucleotide encoding at least one immunogenic portion of an antigen obtained from an intracellular pathogen and administering to said warm-blooded animal at least one protein comprising at least one immunogenic portion of an antigen obtained from said intracellular pathogen.

Craig teaches a method of eliciting an immune response in a mammal comprising administering to said mammal a mixture comprising a nucleic acid encoding a first immunogenic epitope operably linked to transcriptional regulatory elements and a peptide comprising a second immunogenic epitope such that the nucleic acid and the peptide are taken up, wherein the nucleic acid is expressed and an immune response is elicited in the mammal. See the claims and throughout the entire document. Craig further teaches various antigens for use in his methods, in particular Craig teaches use of HIV and hepatitis antigens. See column 21 in the section titled "viral antigens". Furthermore, Craig teaches vaccines, comprising the same mixture, against HIV and hepatitis viruses. See columns 25-28. With respect to gene delivery vehicles, Craig teaches use of retroviruses, adeno-associated viruses (parvovirus), and plasmids as gene delivery vehicles. See columns 11-12 and 17-20. Craig teaches that his methods could be used to generate both prophylactic and therapeutic immune responses, wherein the immune system can be primed and boosted either using the same complex or mixture or using combinations of different complexes or mixtures. See column 24, lines 35-42. This interpreted mean that the antigen component of the mixture may be

administered prior to administration of the gene delivery vehicle. Finally, Craig teaches the addition of immunomodulatory cofactors to the gene delivery vehicle/antigen mixture to induce an immune response. See columns 6-7.

Thus, the teachings of Craig anticipate all of the instant claim limitations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Craig (US 6,689,757) taken with Dubensky et al (5,843,723).

The claims are directed to a method for generating an immune response against one or more intracellular pathogens within warm-blooded animals comprising administering to a warm-blooded animal a gene delivery vehicle vector [retroviral vectors, alphavirus vectors, parvovirus vectors, plasmid vectors, or eukaryotic layered initiation system vectors] comprising a polynucleotide encoding at least one immunogenic portion of an antigen obtained from an intracellular pathogen and administering to said warm-blooded animal at least one protein comprising at least one immunogenic portion of an antigen obtained from said intracellular pathogen.

Craig teaches a method of eliciting an immune response in a mammal comprising administering to said mammal a mixture comprising a nucleic acid encoding

a first immunogenic epitope operably linked to transcriptional regulatory elements and a peptide comprising a second immunogenic epitope such that the nucleic acid and the peptide are taken up, wherein the nucleic acid is expressed and an immune response is elicited in the mammal. See the claims and throughout the entire document. Craig further teaches various antigens for use in his methods, in particular Craig teaches use of HIV and hepatitis antigens. See column 21 in the section titled "viral antigens". Furthermore, Craig teaches vaccines, comprising the same mixture, against HIV and hepatitis viruses. See columns 25-28. With respect to gene delivery vehicles, Craig teaches use of retroviruses, adeno-associated viruses (parvovirus), and plasmids as gene delivery vehicles. See columns 11-12 and 17-20.

Craig does not teach use of alphavirus vectors or eukaryotic layered vector initiation system vectors.

However at the time the claimed invention was made, use of various gene delivery vehicles for transferring heterologous DNA to a host cell was within the routine skill level of the ordinary artisan. In particular, Dubensky et al teach use of alphavirus vectors and eukaryotic-layered vector initiation system vectors for delivering heterologous DNA to host cells.

Accordingly, in view of the routine state of the art of gene delivery vehicles (as presented by Craig and Dubensky, it would have been obvious to use alphavirus vectors or eukaryotic-layered vector initiation system vectors as gene delivery vehicles in the methods of Craig. One of ordinary skill in the art would have been sufficiently motivated to use alphavirus vectors or eukaryotic layered vector initiation system

vectors as gene delivery vehicles because it was an art-recognized goal to deliver heterologous DNA to a host to induce an immune response as per the teachings of Craig and Dubensky.

Thus, the claimed invention, as a whole, was clearly prima facie obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is (571) 272-0732. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS, JR.
PRIMARY EXAMINER

Pete Paras